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(56) Documents Cited

GB 2205499 A EP 0448878 A2 EP 0389272 A2
WO 97/12640 A1 US 5391248 A US 5305743 A
US 5303697 A US 4509514 A

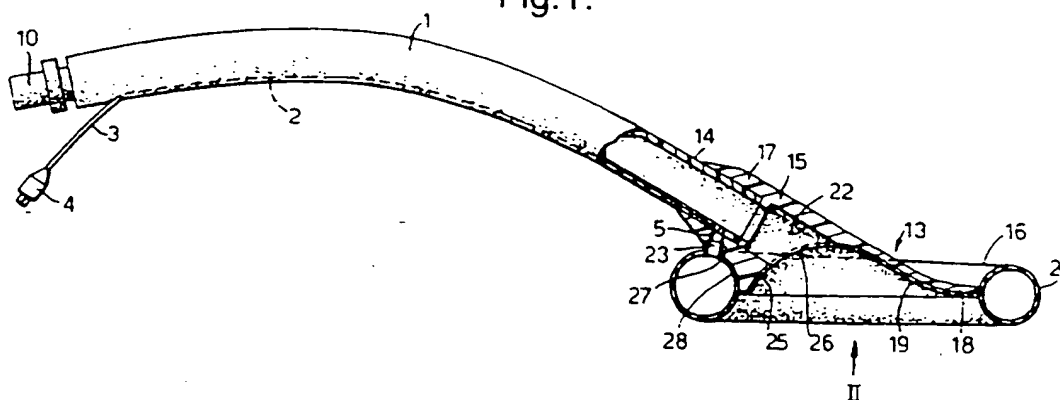
(58) Field of Search

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(54) Laryngeal mask airway and manufacture thereof

(57) A laryngeal mask assembly has a mask portion 13 of elliptical shape formed by a mount 15 and an inflatable member 16 attached to the mount. The inflatable member 16 is formed by heat bonding together opposite walls (31) and (32) of a flat balloon (30) and at the same time cutting an aperture 26 through the walls, so as to form a central web 25 within an outer inflatable ring 24. The central web 25 is attached to a concave surface 19 on the forward surface of the mount 15 with the aperture 26 in the web aligned with an opening 22 in the mount.

Fig.1.



GB 2 318 735 A

Fig.1.

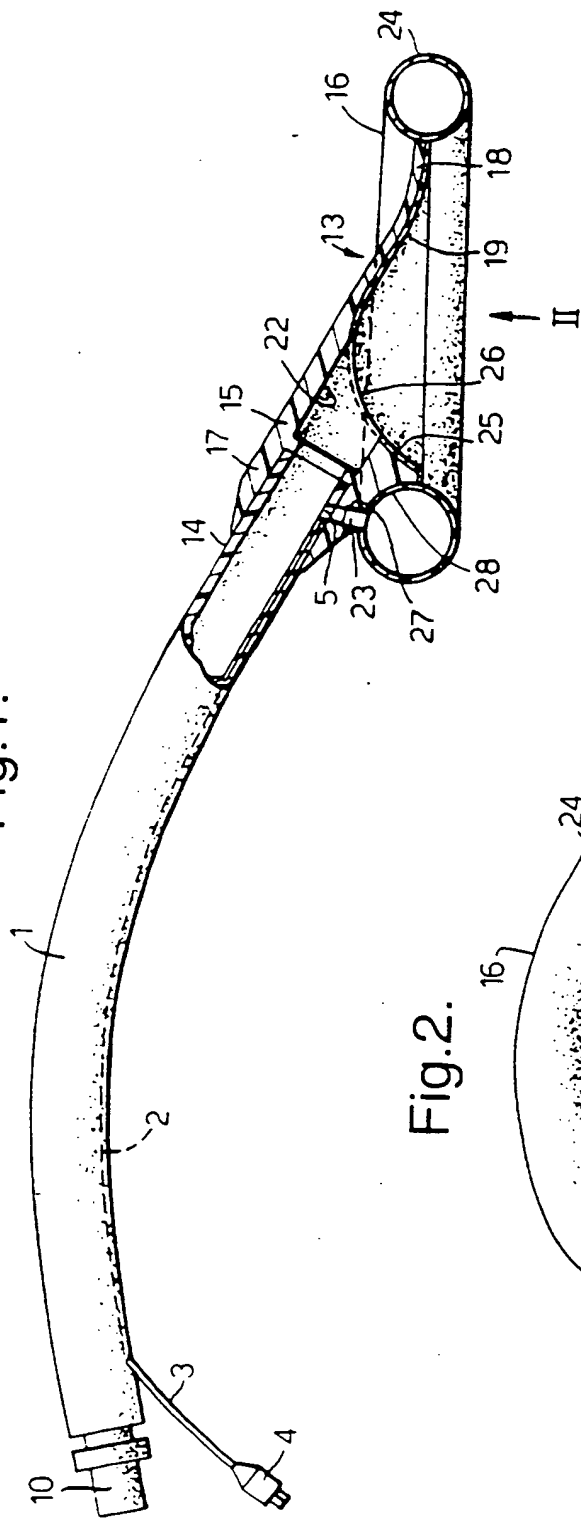


Fig.2.

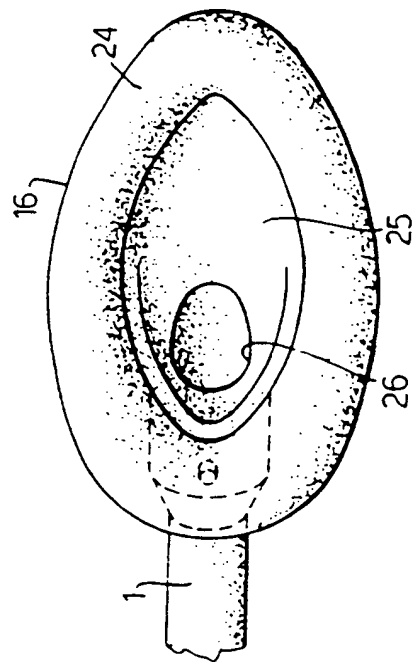


Fig.3.

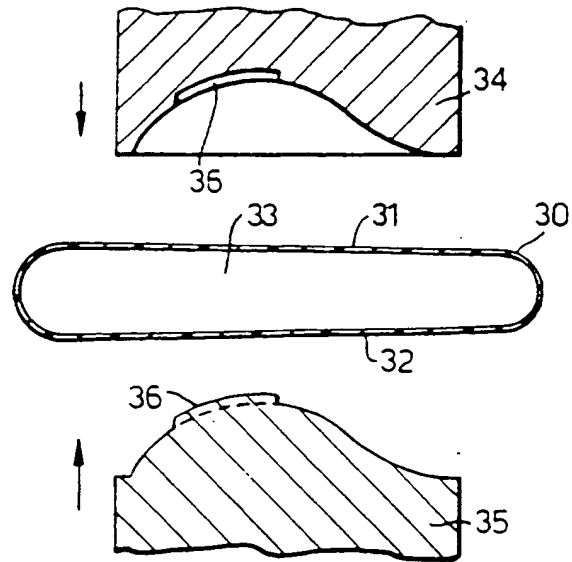
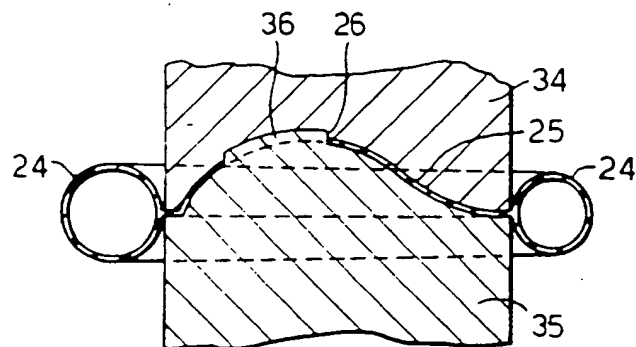


Fig.4.



Laryngeal Mask Airways and their Manufacture

This invention relates to laryngeal mask airways and their manufacture

It is common practice to use an airway known as a laryngeal mask for the administration of anaesthetic and ventilation gases to a patient. These airways comprise a tube with an inflatable mask or cuff at one end, the tube being inserted in the patient's mouth so that one end is located in the hypopharynx and so that the mask forms a seal in this region with the surrounding tissue. Laryngeal masks are described in, for example, US 5355879, US 5305743, US 5297547, US 5282464, GB 2267034, US 5249571, US 5241956, US 5303697, GB 2249959, GB 2111394, EP 448878, US 4995388, GB 2205499, GB 2128561 and GB2298797.

Laryngeal masks have several advantages over endotracheal tubes, which are longer and seal with the trachea below the vocal folds. It can be difficult, however, to manufacture the patient end of the mask at low cost.

It is an object of the present invention to provide an improved laryngeal mask assembly and method of manufacture.

According to one aspect of the present invention there is provided a laryngeal mask assembly including a mask portion and an elongate tube that opens at its forward, patient end into the mask portion, the mask portion being adapted during use to locate in the hypopharynx and to open on its forward side to the patient's airway, the mask portion having a mount member attached with the patient end of the tube, the mount member being generally elliptical, the tube opening at the patient end of the assembly via an opening on the forward

surface of the mount member, the mask portion having an expandable member comprising an expandable ring and a central web extending within said ring, and the web being attached to the forward surface of the mount member and having an aperture therein aligned with the opening in the mount member.

The forward surface of the mount member is preferably concave and the ring may project beyond the outer perimeter of the mount member.

According to another aspect of the present invention there is provided a method of manufacture of a laryngeal mask assembly of the kind including a mask portion and an elongate tube that opens at its forward, patient end into the mask portion, the mask portion being adapted during use to locate in the hypopharynx and to open on its forward side to the patient's airway, the method including the steps of providing a mount member at the patient end of the tube, forming an expandable member comprising an expandable ring and a web within the ring, and attaching the web to the mount member so as to secure the expandable member with the mount member.

The expandable member is preferably formed by providing an expandable balloon and joining opposite walls of the balloon together in a central region such that the region where the walls are joined together provides the web and the remainder of the balloon provides the expandable ring. The opposite walls are preferably joined together by heat sealing. The opposite walls may be joined together using a die on opposite sides of the balloon, the dies being provided with cutting formations to form an aperture in the web.

A laryngeal mask assembly and its method of manufacture, according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a partly-sectional side elevation view of the assembly;

Figure 2 is a view of the forward end of the assembly along the arrow II of Figure 1;

Figures 3 and 4 illustrate steps in the manufacture of the inflatable member.

With reference to Figures 1 and 2, the assembly comprises a bendable tube 1 of a plastics material, such as PVC, with a coupling 10 at its machine end 12. The tube 1 is curved along its length and has a mask portion 13 at its patient end 14.

The tube 1 is extruded with an inflation lumen 2 within its wall. The lumen 2 is connected towards the machine end of the assembly to an inflation line 3 with an inflation indicator and connector 4. The opposite, patient end of the inflation lumen 2 opens into the mask portion 13, through a hole or slot 5 formed in the outside of the tube 1.

The mask portion 13 comprises a mount member 15 and an expandable or inflatable assembly 16. The mount member 15 is moulded from a relatively stiff plastics material, such as PVC. The mount member 15 has a hollow cylindrical sleeve 17 at its rear end, in which the forward, patient end of the tube 1 is inserted and joined. The forward, patient end 18 of the mount member 15 is of an inverted dish shape with a generally elliptical or egg-shape outline and with a concave surface or recess 19. A bore 22 extends forwardly through the mount member 15, as a continuation of the bore through the sleeve 17, and forms an opening into

the rear part of the recess 19. The hole or slot 5 in the tube 1 opens into a passage 23 through the mount member 15.

The inflatable assembly 16 comprises an expandable or inflatable outer ring 24 of circular section and egg shape with an integral, flexible, central web 25 within the ring. The ring 24 could have other shape sections, such as oval or elliptical. The diameter of the ring 24 towards the rear, machine end is slightly greater than that at the forward, patient end. The web 25 has the same shape as the underside of the mount member 15, that is, it is concave when viewed from beneath. An aperture 26 through the web 25 is aligned with the opening of the bore 22 in the mount member 15. A spigot 27 projects upwardly from the ring 24 and is sealed within the passage 23 in the mount member 15 so that the inflation lumen 2 opens into the ring 24. The inflatable member 16 is attached to the mount member 15 by means of an adhesive between the upper surface of the web 25 and the surface of the recess 19 so that the ring 24 projects beyond the mount member around its perimeter. Adhesive is also applied in the region of the passage 23, where the mount member has a shallow concave recess 28 shaped to receive a part of the ring 24 around the spigot 27.

The inflatable member 16 can be readily manufactured from a flexible plastics material, such as PVC, polyurethane, silicone, EVA, TPE, polyether block amide or the like. In one method of manufacture, a flat balloon 30 is first blow moulded having the egg-shape outline of the assembly but with substantially flat upper and lower surfaces 31 and 32 and an open interior 33, as shown in Figure 3. The balloon 30 is then placed between two dies 34 and 35, which are brought together to force the upper and lower surfaces 31 and 32 into contact in the central region only, leaving the surfaces separate in the peripheral region, as shown in Figure 4. The dies 34 and 35 are heated so that the upper and lower surface heat bond together in the central region to form the web 25, the peripheral region outside the central region forming the inflatable ring. Alternatively, the bond could be made by RF welding. The

die surfaces have complementary profiles, defining the finished shape of the web, and cutting edges 36 to form the aperture 26 in the web. The spigot 27 may be formed during the initial blow moulding process or attached subsequently. The aperture 26 could have a series of holes or slits to prevent entry of the epiglottis.

The airway can be easily manufactured in this way at low cost.

The expandable member 16 could contain a foam material so that it naturally adopts an inflated or expanded state and is deflated by the action of suction. The foam may be inserted in the ring after attaching the expandable member to the mount member.

CLAIMS

1. A laryngeal mask assembly including a mask portion and an elongate tube that opens at its forward, patient end into the mask portion, the mask portion being adapted during use to locate in the hypopharynx and to open on its forward side to the patient's airway, wherein the mask portion has a mount member attached with the patient end of the tube, the mount member being generally elliptical, wherein the tube opens at the patient end of the assembly via an opening on the forward surface of the mount member, wherein the mask portion has an expandable member comprising an expandable ring and a central web extending within said ring, and wherein the web is attached to the forward surface of the mount member and has an aperture therein aligned with the opening in said mount member.
2. A laryngeal mask assembly according to Claim 1, wherein the forward surface of the mount member is concave.
3. A laryngeal mask assembly according to Claim 1 or 2, wherein the ring projects beyond the outer perimeter of the mount member.
4. A laryngeal mask assembly substantially as hereinbefore described with reference to the accompanying drawings.

5. A method of manufacture of a laryngeal mask assembly of the kind including a mask portion and an elongate tube that opens at its forward, patient end into the mask portion, the mask portion being adapted during use to locate in the hypopharynx and to open on its forward side to the patient's airway, the method including the steps of providing a mount member at the patient end of the tube, forming an expandable member comprising an expandable ring and a web within the ring, and attaching the web to the mount member so as to secure the expandable member with the mount member.
6. A method according to Claim 5, wherein the expandable member is formed by providing an expandable balloon and joining opposite walls of the balloon together in a central region such that the region where the walls are joined together provides said web and the remainder of the balloon provides said expandable ring.
7. A method according to Claim 6, wherein the opposite walls of the balloon are joined together by heat sealing.
8. A method according to Claim 6 or 7, wherein the opposite walls are joined together using a die on opposite sides of the balloon, and wherein the dies are provided with cutting formations to form an aperture in the web.
9. A method of manufacture of a laryngeal mask assembly substantially as hereinbefore described with reference to the accompanying drawings.

10. A laryngeal mask assembly made by a method according to any one of Claims 5 to 9.
11. Any novel and inventive feature as hereinbefore described.



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Office

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Application No: GB 9722394.5
Claims searched: 1-10

Examiner: Dr J. P. Bellia
Date of search: 25 February 1998

Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.P): A5R (RGEX)

Int CI (Ed.6): A61M 16/00, 16/04

Other: ONLINE: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	GB 2205499 A (BRAIN) See Figure 3 & page 5 line 14-page 6 line 14	1-5 & 10
X	EP 0448878 A2 (BRAIN) See Figure 3 & column 4 line 47-column 5 line 16	1-5 & 10
X	EP 0389 272 A2 (BRAIN) See Figure 3 & column 5 line 13-50	1-5 & 10
P.X	WO 97/12640 A1 (BRAIN) See Figures 4, 5 & page 8 line 18 - page 9 line 17	1-5 & 10
X	US 5391248 (BRAIN) See Figures 1-4 & column 4 line 21 - column 7 line 29	1-5 & 10
X	US 5305743 (BRAIN) See Figures 1-4 & column 4 line 16 - column 7 line 24	1-5 & 10
X	US 5303697 (BRAIN) See column 3 line 29-38 & Figure 3	1-5 & 10
X	US 4509514 (BRAIN) See column 2 line 28 - column 3 line 4	1,3-5 & 10

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.
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P Document published on or after the declared priority date but before the filing date of this invention.
E Patent document published on or after, but with priority date earlier than, the filing date of this application.